UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,255	11/12/2003	Ondrej Hendl	PC027453	6868

25533 7590 03/13/2009

PHARMACIA & UPJOHN
7000 Portage Road
KZO-300-104
KALAMAZOO, MI 49001

EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,255	HENDL ET AL.	
	Examiner	Art Unit	
	ROY TELLER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,12,13,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12-13,16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 12/18/08, in which claim 1 was amended.

Claims 1-8, 12-13 and 16-17 are under examination.

Response to Amendments/Arguments

Applicant's arguments and amendments, filed 12/18/08, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 12-13 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a bioactive substance comprising crystalline ceftiofur free acid (CCFA), does not reasonably provide enablement for a composition comprising one to three bioactive agents wherein one to three bioactive agents is selected from the group consisting of pharmaceuticals, immunogenic and immunomodulator compositions, vectors, viruses, spores, nutritional supplements and bacteria and mixtures thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors

indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a composition comprising one to three bioactive agents wherein one to three bioactive agents is selected from the group consisting of pharmaceuticals, immunogenic and immunomodulator compositions, vectors, viruses, spores, nutritional supplements and bacteria and mixtures thereof.

The breadth of the claims is excessive with regard to claiming a composition comprising one to three bioactive agents wherein one to three bioactive agents is selected from the group consisting of pharmaceuticals, immunogenic and immunomodulator compositions, vectors, viruses, spores, nutritional supplements and bacteria and mixtures thereof.

Applicant has only provided guidance for the use of a composition comprising a bioactive substance comprising crystalline ceftiofur free acid (CCFA). Applicant have provided no guidance for the use of any other ingredient in the instant specification.

It would not be predictable to the artisan which ingredient would work in the present invention, nor would it be predictable to the artisan which pathologies could be treated with these ingredients

In consideration of these factors, it is apparent that there is undue experientation because of a variability in prediction of outcome that is not addressed by the present application.

Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than using crystalline ceftiofur free acid (CCFA to provide the functional effects instantly claimed, as shown in instant examples 2, 4-6, page 13, 16 and 18, and figure 2, page 17.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, first paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 12-13 and 16-17 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn (USPN 5,721,359) in view of Foster (USPN 5,736,151)for the reasons of record which are restated below.

The claimed invention is drawn to a composition comprising a bioactive pharmaceutical or specifically, crystalline ceftiofur free acid (CCFA) and one or more modified oils selected from corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil, or coconut oil as the liquid carrier. "Modified" is understood to mean a vehicle which, through physical, chemical or mechanical means, has been altered as compared to its natural (or "non-modified" in the case of synthetic liquid carriers) form such that the modified vehicle has an increased level of oxidation products. Modification is accomplished by heat or irradiation, among other means. The composition is administered to a host, wherein the concentration of crystalline ceftiofur free acid ranges from about 50 mg/ml to about 250 mg/ml, and the composition is released to the host on a predictable sustained basis.

Dunn teaches crystalline ceftiofur free acid as the cephalosporin antibiotic ceftiofur, see abstract and claim 1, column 17. Dunn discloses a composition with a pharmaceutically acceptable carrier, see claim 8, column 19. Dunn teaches that the composition is sustained-release, see claim 9, column 19. Dunn discloses the composition as comprising from about 20 to 200 mg/ml of crystalline ceftiofur free acid, see claim 10, column 19. Dunn teaches the composition is nonaqueous, where the nonaqueous composition is an oil, selected from the group consisting of corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil,

sunflower oil and mixtures thereof, see claims 12, 13, and 14, column 19. Dunn teaches modifying the oil carrier by heat or irradiation in order to render it sterile, see column 8, lines 42-50.

Dunn teaches a pharmaceutical composition comprising crystalline ceftiofur free acid and a modified carrier as set forth *supra.* Dunn does not teach the use of coconut oil as in the claimed invention.

Foster teaches a composition where the drug is a cephalosporin, see claim 16, column 14. Foster discloses oil used in the composition as selected from the group consisting of canola oil, corn oil, cottonseed oil, olive oil, peanut oil, sesame oil, soybean oil, safflower oil, coconut oil, sunflower oil and palm oil, see claim 19, column 14. Foster teaches a volume of 90% heated cottonseed oil used in the preparation of the composition, see column 10, lines 26-28. Foster discloses the present invention provides for novel formulations, such as oil suspensions, see column 1, lines 6-7.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the coconut oil of Foster in the composition of Dunn as the equivalent of one or more of the vegetable oils disclosed by Dunn. While Foster does not specifically teach an amount of cottonseed oil with coconut oil in the composition, absent some evidence to the contrary, the claimed ratios of oil constitute routine optimization of a known composition.

Applicant's arguments were carefully considered but were not found persuasive. Applicant contends that ethylene oxide sterilization is not desirable in a pharmaceutical product. The examiner agrees with this statement, however, the examiner contends that

the Dunn reference discloses heat as a method of sterilization. This method of sterilization would be a method of modifying the carrier. See, for example, column 8, lines 42-50. Applicant contends that the solid preparation is a dry, solid preparation. However, the examiner contends that Dunn discloses liquid preparations in suitable liquid vehicles. See, for example, column 8, lines 14-20

Applicant contends that the compositions of Dunn do not provide sustained release performance of the composition in the same sense as the compositions of the instant invention. However, the examiner contends that Dunn teaches that the composition is sustained release. See, for example, claim 9, column 19. Applicant further contends that the prior art does not teach a peroxide value of the modified liquid carrier (the heated cottonseed oil). However, the examiner contends that since Dunn discloses the use of heat, that a peroxide value would be inherent in the modified liquid carrier.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT

/Christopher R. Tate/
Primary Examiner, Art Unit 1655